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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,503	02/06/2006	Ryouichi Hoshino	2006-0019A	7559

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,503	HOSHINO ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 - 5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 - 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 23, 2009 has been entered.

Response to Amendment

2. The declaration under 37 CFR 1.132 filed April 23, 2009 is sufficient to overcome the rejection of claims 3 - 5 based upon Ohyama (EP 1245232).

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 3 - 5 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/795792 in view of Alderman (US 4,734,285). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 22, 2008 and those set forth below.

Applicants have requested that this rejection be held in abeyance until the claims are indicated as otherwise allowable.

Therefore this rejection is maintained for the reasons of record. A new claim limitation of an average viscosity of 4000 cps for the HPMC has been added. In Example 3 of Alderman, METHOCEL® E-4M (HPMC 2910) was used in the solid tablets as the sustained release material (col 5, ln 57 – 61). This material has a viscosity of 4000 cps (see col 4, ln 37 – 41 of US 4,803,079).

Response to Arguments

5. Applicant's arguments with respect to claims 3 – 5 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 3 – 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal (US 5,399,359) in view of Miyachi et al. (Bioorganic & Medicinal Chemistry 1999) and Alderman (US 4,734,285).

Baichwal discloses solid oral sustained release formulations of oxybutynin (col 1, ln 55 – 58), an active agent which is has an anti-spasmodic effect and thus is useful for the relief of symptoms of bladder instability associated with voiding of the bladder (col 2, ln 60 – col 3, ln 1). Controlled release of the active ingredient allows the desired blood levels of active ingredient to be maintained for a comparatively long period of time while increasing patient compliance as fewer administrations are required to achieve the same effect (col 1, ln 7 – 12). The controlled release is achieved through the use a

matrix comprised of a gelling agent, a water-soluble cationic cross-linking agent and an inert diluent (col 1, ln 67 – col 2, ln 6). Typical dosages of oxybutynin are about 5 to about 20 mg (col 3, ln 5 – 8).

Baichwal does not disclose 4-(2-methyl-1-imidazolyl)-2,2-diphenylbutylamide (KRP-197) or hydroxypropylmethylcellulose (HPMC) as being present in the composition.

Miyachi et al. discloses that the inhibitory action of KRP-197 on bladder contractions is 15 – 19 times more potent of an inhibitor of bladder contractions than oxybutynin with effective dosages ranging from 0.020 – 0.20 mg/kg with a similar duration of action (p 1157, col 1, ¶ 2), and more selective for bladder tissue over other tissues in the body than oxybutynin (p 1157, col 2, ¶ 2).

Alderman discloses that delayed release solid tablets can be prepared using HPMC (col 1, ln 61 – 65). The amount of HPMC in the dosage form typically ranges from about 5 to about 90 percent (col 3, ln 3 – 9). In Example 3, METHOCEL® E-4M (HPMC 2910) was used in the solid tablets (col 5, ln 57 – 61). This material has a viscosity of 4000 cps (see col 4, ln 37 – 41 of US 4,803,079).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to prepare a sustained release dosage form of KRP-197. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because Miyachi et al. discloses that KRP-197 exhibits more potency and specificity for bladder tissue than oxybutynin. It also would have been obvious to the person of ordinary skill in the art at

the time the invention was made to use HPMC with a viscosity of 4,000 cps as the controlled release agent. A person of ordinary skill in the art would have been motivated to make those modifications as a single ingredient controlled release matrix that does not require cross-linking will be easier to prepare in a consistent manner and reasonably would have expected success because Alderman teaches that HPMC of the claimed viscosity can be used as a controlled release matrix for solid oral formulations.

The amount of HPMC in the composition taught by Alderman overlaps with that claimed be Applicant. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 **MPEP 2144.05** The amount of active ingredient claimed by Applicant is less than that disclosed by Baichwal. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. In this case, Miyachi et al. discloses that KRP-197 is much more potent than oxybutynin, so a smaller dose would be required to achieve the same effect.

Claims 4 and 5 are product-by-process claims."[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. The process of the claims results in a solid oral tablet in which the active ingredient is dispersed throughout the HPMC matrix. The process taught by Alderman results in a solid oral tablet in which the active ingredient is dispersed throughout the HPMC matrix. Therefore the products produced by the process of the instant claims and Alderman are the same and claims 4 and 5 are not patentably distinguished over the cited prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW